

REMARKS

Upon entry of this Amendment, Claims 21-22, 26, 28-29, 46-55, 57, 61-67, and 96-109 are pending herein. By this Amendment, non-elected Claims 1-20, 23-25, 27, 30-46, 56, 58, and 68-95, are canceled, without prejudice or disclaimer; Claims 21-22, 26, and 103 are amended; and new Claims 107-109 are added. Support for the claim amendments and new claims is found in the specification at, *inter alia*, page 10, lines 10-15 and page 11, lines 15-18. No new matter is added by this Amendment.

I. RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS

Upon entry of this Amendment, the claims readable upon the elected species are Claims 21-22, 26, 29, 47-52, 54-55, 57, 66-67, 96-97, 99, and 101-109.

Contrary to the assertion in the Office Action, Applicants still traverse the restriction requirement and set forth reasons why the restriction requirement is in error in the Amendment filed on July 1, 2002. To reduce the number of issues, however, Applicants have canceled the non-elected method claims, without prejudice or disclaimer. For the reasons set forth in the Amendment filed on July 1, 2002, Applicants respectfully request that product Claims 28, 46, and 61-65 also be examined.

Applicants responded without traverse on November 22, 2002 to the election of species requirement dated November 6, 2002 regarding the hydrophobic agent. Once the pending claims are found allowable search and examination must continue as to the non-elected species of encapsulants, such as enzymes and probiotics. Thus, Claims 53, 98, and 100 have not been canceled.

II. SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENTS

Without providing any reason, the Examiner stated on page 4 of the final Office Action that the Supplemental IDS filed July 25, 2002 [sic: July 1, 2002] and the

Supplemental IDS filed March 22, 2002 [sic: March 8, 2002] are not of record. In a May 7, 2003 telephone conference with Examiner Webman, he indicated that some of the references cited in those IDS's were not properly matched with the file at the U.S. Patent and Trademark Office. Thus, Applicants resubmit the missing cited references in a Resubmission of Supplemental IDS filed concurrently herewith and respectfully request that the references be considered and made of record.

II. FORMAL MATTERS

Claims 21-22, 47-52, 54, 66-67, 96-97, 99, and 101-106 were rejected under 35 U.S.C. 112, second paragraph, as assertedly being indefinite.

Applicants respectfully note that the word "substantially" is not indefinite. See MPEP 2173.05(b)(D). A copy of this MPEP section is attached for the Examiner's convenience.

In support of the Examiner's position that the term "substantially" is indefinite, he cited one case from a district court, *E.W. Bliss v. Cold Metal Process Co.*, 174 F. Supp. 99, 122 USPQ 238 (N.D. Ohio 1959). However, the Examiner's assertion that the term "substantially" may be "as much as 49%" is not in accordance with the particular facts of that case. In *E.W. Bliss*, the district court relied upon the statements in the file history to hold that the claimed limitation "driven substantially by tension on the strip" does not extend to tension supplying 49% of the total power. See *E.W. Bliss*, 174 F. Supp. at 125. In addition, the court noted that the word "substantial" does not connote small or meager. Id. Rather, it includes the "high range of principally or entirely." Id.

In the previous Amendment, Applicants cited numerous recent cases from the Federal Circuit, which has authority over district courts such as that in *E.W. Bliss*, to demonstrate that the term "substantially" is definite without any quantitative or numerical definition, so long as one of ordinary skill in the art understands what is claimed. See

York Products, Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568, 1573 (Fed. Cir. 1996); *Pall Corp. v. Micron Seps.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995); *Andrew Corp. v. Gabriel Elecs. Inc.*, 847 F.2d 819 (Fed. Cir. 1988). One of ordinary skill in the art would understand that the term “substantially” as claimed means “principally or entirely”. See, for example, page 7, lines 13-25, page 13, lines 24-31, page 14, line 28 - page 15, line 4, and page 27, lines 18-23 of the present specification. Accordingly, the scope of Claims 21-22, 47-52, 54, 66-67, 96-97, 99, and 101-106 would be reasonably ascertainable to one of ordinary skill in the art when read in light of the specification. Thus, the requirements of 35 U.S.C. 112, second paragraph, are satisfied. Reconsideration and withdrawal of the rejection are respectfully requested.

III. REJECTION UNDER 35 U.S.C. 103(a)

Claims 21-22, 26, 29, 47-52, 54-55, 57, 66-67, 96-97, 99, and 101-106 were rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,320,669 (Lim et al.) in view of U.S. Patent No. 5,716,615 (Cavaliere Vesely et al.). This rejection is respectfully traversed.

A. LIM ET AL.

Lim et al. discloses a biodegradable thermoplastic composition made of a cereal grain, such as durum wheat, and which may also contain lubricant additives, such as fatty acids or vegetable oils (col. 6, lines 7-26). The cereal grain may be nutritionally reinforced with vitamins or minerals (col. 3, lines 35-39). The edible composition may also contain an edible flavoring agent or an antimicrobial agent (col. 7, lines 5-14). There is no disclosure regarding the amount of vitamins, minerals, flavoring agent, or antimicrobial agent. The molded articles may be in the form of capsules, trays, or bottles. The molded articles may be used for packaging drugs (col. 9, lines 6-14).

Lim et al. does not teach or suggest an encapsulated product comprising a substantially homogeneous mixture of: (1) at least one matrix material, (2) about 1 wt.% to about 85 wt.% of an encapsulant based upon the weight of the matrix material, and (3) a hydrophobic agent, as recited in Claim 21. Lim et al. does not teach or suggest the encapsulants recited in Claims 22 and 26. Further, Lim et al. does not teach or suggest an encapsulated product comprising an encapsulant selected from the group consisting of live lactobacilli, a probiotic, a prebiotic, and an enzyme, wherein a liquid encapsulant component comprising the encapsulant and a liquid plasticizer provides at least a substantial portion of liquid plasticizer for forming the at least one plasticized matrix material, as recited in Claim 104 and its dependent claims.

The Examiner stated in the Office Action that the “various components of the Lim et al. composition will achieve the claimed homogeneity”. However, there is no teaching or suggestion to support this assertion. The molded compositions of Lim et al. serve to package drugs, for example, in capsules or bottles. Thus, there are separate entities which do not form a mixture in Lim et al.: (1) the molded article comprising a cereal grain composition, and (2) a packaged drug. Lim et al. does not teach or suggest an encapsulated product comprising a substantially homogeneous mixture of a plasticized matrix material and about 1 wt.% to about 85 wt.% of an encapsulant (e.g., a probiotic), based upon the weight of the matrix material. Unlike Lim et al., the claimed encapsulant is at least substantially uniformly distributed in the plasticized matrix material.

B. CAVALIERE VESELY ET AL.

Cavaliere Vesely et al. does not overcome the deficiencies of Lim et al. Cavaliere Vesely et al. discloses a pharmaceutical composition containing several different bacteria including *Streptococcus thermophilus* and *Lactobacillus plantarum* or *Lactobacillus*

casei. The compositions may be made in conventional pharmaceutical forms, such as tablets or capsules (col. 3, lines 19-21).

Even if Lim et al. and Cavaliere Vesely et al. were properly combinable, Applicants' claimed encapsulated product would not be obtained. Any such combination would not result in a substantially homogeneous mixture of a plasticized matrix material and an encapsulant, as recited in Claim 21. Instead, such a combination would yield a non-homogenous combination of a capsule made of a cereal grain composition that is separate and distinct from the packaged bacteria. Cavaliere Vesely et al. also does not teach or suggest: (1) that a liquid encapsulant component comprising the encapsulant and a liquid plasticizer provides at least a substantial portion of liquid plasticizer for forming the at least one plasticized matrix material, as recited in Claim 104; or (2) that an encapsulant is at least substantially uniformly distributed in the plasticized matrix material, as recited in Claim 107. There is no teaching or suggestion whatsoever in Lim et al. or Cavaliere Vesely et al. to admix a matrix material with a liquid *lactobacillus* encapsulant to form a plasticized matrix material. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed encapsulated products in view of the combined teachings of Lim et al. and Cavaliere Vesely et al. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. DOUBLE PATENTING

To avoid any question of double patenting, Applicants will file a Terminal Disclaimer over U.S. Patent 6,500,463 B1 if required by the Examiner.

V. CONCLUSION


In light of the foregoing remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions

van Lengerich - Serial No. 09/233,443
AMENDMENT AFTER FINAL REJECTION UNDER 37 C.F.R. 1.116
AND SUMMARY OF TELEPHONIC INTERVIEW WITH EXAMINER

regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

Any shortages in fees should be charged to, or any overpayment in fees should be credited to, Deposit Account No. 501032 (Docket #BVL-105).

Respectfully submitted,

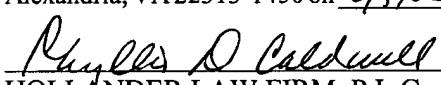

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June 5, 2003

Enclosure:
MPEP 2173.05(b)(D) (Aug. 2001)

<p align="center">CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence dated <u>6/5/03</u> is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on <u>6/5/03</u>.</p> <p align="center"> HOLLANDER LAW FIRM, P.L.C. Suite 305 10300 Eaton Place Fairfax, Virginia 22030</p> <p>Date: <u>6/5/03</u></p>
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